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मानक

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IS 11640-5 (1987): Retractor, Part 5: Korte's Pattern [MHD
1: Surgical Instruments]



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“ज्ञान एक ऐसा खजाना है जो कभी चुराया नहीं जा सकता है”

Bhartrhari—Nitiśatakam

“Knowledge is such a treasure which cannot be stolen”

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Indian Standard

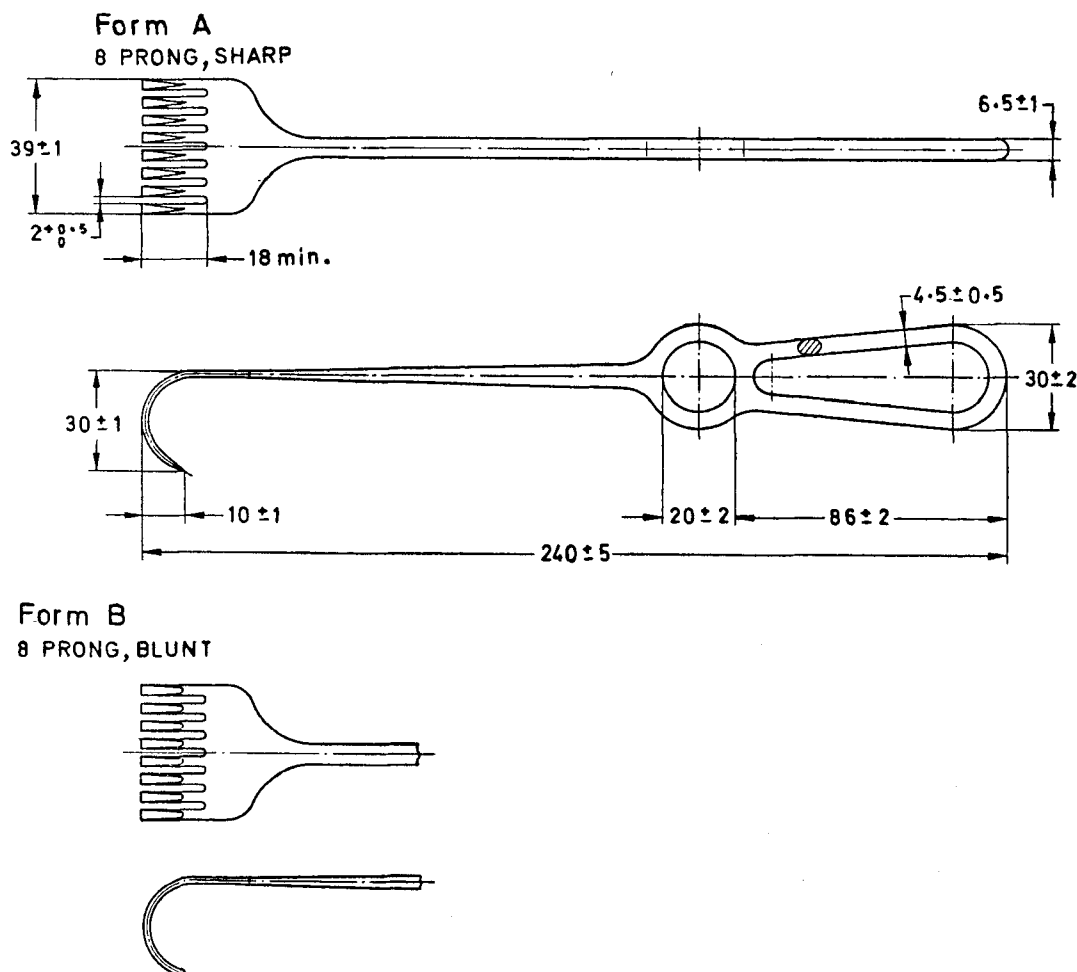
(Reaffirmed 1998)

SPECIFICATION FOR
RETRACTOR

PART 5 KORTE'S PATTERN

1. Scope — Specifies dimensional and other requirements of Korte's pattern retractors used in general surgery.

2. Shape and Dimensions — As shown in Fig. 1.



Mass = 140 g approx

All dimensions in millimetres.

FIG. 1 RETRACTOR, KORTE'S PATTERN

3. Material — Stainless steel conforming to Designation 20Cr13 or 30Cr13 of IS:6603-1972 'Specification for stainless steel bars and flats'.

4. Requirements

4.1 Heat Treatment and Hardness — The retractor shall be heat treated to give a hardness of 390-485 HV.

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4.2 Workmanship — The retractor shall be free from burrs, pits, cracks and other surface defects. The edges of the blade shall be properly rounded.

4.3 Surface Condition — All surfaces shall be free from pores, crevices and grinding marks. The retractor shall be supplied free from residual scale, acid, grease and grinding and polishing materials. Compliance with these requirements shall be checked by inspection using normal vision (corrected, if necessary).

4.4 Surface Finish — The surface finish shall be one or a combination of the following:

- a) Mirror polished;
- b) Reflection-reducing, for example, satin finish, matt black finish; and
- c) An applied surface coating, for example, for insulation purposes.

Note — The satin finish should be effected by an appropriate procedure, such as grinding, brushing, electropolishing and, in addition, satin finishing (glass beading or satin brushing). The finish should be uniform and smooth and it should reduce glare. Instrument of mirror finish should be adequately ground to remove all surface imperfections and polished to remove grinding marks, resulting in a mirror finish. The mirror finish should be effected by an appropriate procedure, such as polishing, brushing, electropolishing, and mirror buffing.

4.5 Passivation and Final Treatment — The retractor shall be treated by a suitable passivation process.

Note 1 — Examples of methods of passivation are by electropolishing or by treating with 10 percent (v/v) nitric acid solution for not less than 30 minutes at a temperature of not less than 10°C and not exceeding 60°C. The retractor should then be rinsed in water and dried in hot air.

Note 2 — If the joints are lubricated, the lubricant should be non-corrosive and suitable for medical application according to the Indian pharmacopoeia.

5. Tests

5.1 Rigidity Test

5.1.1 The retracting part of the blade shall be applied to the edge of a chair or table. It shall be pulled manually by exerting a maximum force along the axis of the handle. The retractor shall show no sign of damage or permanent set.

5.1.2 A force of 250 N shall be applied at the top of the turned end of the retracting blade. The maximum force shall be gradually attained and maintained for 2 minutes. On completion of the test the retractor shall show no sign of damage.

5.2 Corrosion Resistance — Test the retractor in accordance with IS:7531-1975 'Method for boiling and autoclaving test for corrosion resistance of stainless steel surgical instruments'. The retractor shall show no sign of corrosion after the test.

6. Marking — Each retractor shall be marked with the following:

- a) Manufacturer's name, initials or recognized trade-mark; and
- b) The words 'Stainless Steel'.

6.1 Certification Marking — Details available with the Bureau of Indian Standards.

7. Packing — Each retractor may be wrapped in a moisture-proof paper or put in a polyethylene bag and packed in cardboard cartons. The retractor may also be packed as agreed to between the purchaser and the supplier.

8. Sampling — Sampling procedures and acceptance criteria for conformity shall be as agreed to between the purchaser and the supplier. A recommended scheme for the same is given in Appendix A.

APPENDIX A

(Clause 8)

SAMPLING PLAN AND CRITERIA FOR CONFORMITY

A-1. LOT

A-1.1 In a consignment, all the retractors of the same pattern and dimensions shall be grouped together to constitute a lot, not exceeding 50 items. Each lot shall be tested for the requirements of this specification.

A-2. SCALE OF SAMPLING AND CRITERIA FOR CONFORMITY

A-2.1 Eight retractors shall be selected at random from each lot by using random number tables (see IS:4905-1968 Methods for random sampling). Each retractor in the sample shall be individually tested for the requirements of shape and dimensions (2), material (3), workmanship and finish (4.2 to 4.4), and marking (6). Any retractor failing to meet one or more of the above requirements shall be termed as defective. No defective retractor in the sample shall be permitted, if the lot is to be accepted in this clause.

A-2.2 The lot which has been found satisfactory according to A-2.1 shall be tested for hardness (4.1), rigidity (5.1), and corrosion resistance test (5.2). For this purpose, one retractor shall be sampled at random and tested for the above requirements. If need be, more retractors may be drawn for conducting the relevant tests.

A-2.2.1 No failure shall occur if the lot is to be declared acceptable under this clause.

EXPLANATORY NOTE

This part of Indian Standard is one of the series of Indian Standards on retractors. In the preparation of this standard, assistance has been derived from DIN 58287-1983 'Retractors, type Korte', issued by Deutsches Institut für Normung W.G.